

Notice of Allowability

Application No.

10/790,790

Applicant(s)

KONO ET AL.

Examiner

Art Unit

Brian S. Kwon

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 05/08/06.
2. ☒ The allowed claim(s) is/are 1 and 2.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 10/129,361.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 03/03/04, 04/23/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 05102006.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.


Brian Kwon
Patent Examiner
AU 1614

DETAILED ACTION

Examiners Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Raymond C. Stewart on May 10, 2006.

The application has been amended as follows:

Amendment to the specification:

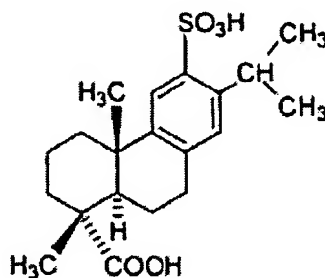
The title of the invention, "Agent for prophylaxis or treatment of inflammatory bowel disease", is replaced with "A method for treatment of peripheral inflammation of a loop ileal artificial anus".

In the Specification, the first paragraph after the title of the invention, replace the preliminary amendment filed 03/03/04 with --The instant application is a divisional of U.S. Application No. 10/129,361, filed on May 3, 2002, patented US 6,730,702, which claims priority to PCT/JP00/07855, filed on November 9, 2000, which claims priority to Japanese Application No. 321058/1999, filed on November 11, 1999 and Japanese Application No. 2000-225442, filed on July 26, 2000--.

Amendment to the claims:

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- Claim 1. A method for treatment of peripheral inflammation of a loop ileal artificial anus in a patient having inflammatory bowel disease, which comprises administering to the patient in need thereof an effective amount of a



compound of the formula (I) or a pharmaceutically acceptable salt thereof to treat said peripheral inflammation of a loop ileal artificial anus, wherein said composition is administered rectally thru the artificial anus.

- Claim 2. The method for treatment of according to claim 1, wherein the pharmaceutically acceptable salt of the compound of the formula (I) is sulfodehydroabietic acid monosodium salt.

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: The instantly claimed composition containing a compound of the formula (I) or a salt thereof are known to exhibit an inhibitory activity of acid secretion or pepsin secretion and to be useful as anti-ulcerative agent for the treatment of peptic ulcer or gastritis (JP 10109942; Ohkusa et al., "Disappearance of hyperplastic polyps in the stomach after eradication of *Helicobacter pylori*: A randomized, controlled trial", *Annals of Internal Medicine*, 1998, 129(9), 712-715; Ohkusa et al.,

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“Prospective evaluation of a new anti-ulcer agent, ecabet sodium, for the treatment of *Helicobacter pylori* infection”, *Alimentary Pharmacology and Therapeutics*, 1998, 12(5), 457-461; JP-A-58-77814, JP-A-63-165361; JP-A-2-167258). However, the prior art reference(s) alone or in combination does/do not teach or suggest the use of said compound in the treatment of peripheral inflammation of a loop ileal artificial anus in patient having inflammatory bowel disease because the treatment of peripheral inflammation of the artificial anus is distinctive from peptic ulcer or gastritis because of their different nosogenesis and lesion regions, and the therapeutic treatment of peptic ulcer or gastritis is different from the treatment of peripheral inflammation of the artificial anus.

Conclusion

3. Claims 1 and 2 are allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in dark ink, appearing to read 'B. Kwon', followed by a long horizontal line extending to the right.